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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,695

02/04/2004

Paul D. Hanke

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03/17/2009

BUCHANAN INGERSOLL & ROONEY PC  
(ARCHER DANIELS MIDLAND COMPANY)  
301 GRANT STREET, 20TH FLOOR  
PITTSBURGH, PA 15219

EXAMINER

KIM, ALEXANDER D

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/771,695	<b>Applicant(s)</b> HANKE ET AL.	
	<b>Examiner</b> ALEXANDER D. KIM	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19,20,22-24,33-35 and 37-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19,20,22-24,33-35 and 37-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-Final rejection (mailed on 06/13/2008), Applicants filed a response and amendment received on 09/16/2008. Said amendment cancelled Claims 1-18, 21, 25-32 and 36; amended Claims 19, 24, 33-35 and 37; and added new Claims 38-47.

Claims 19-20, 22-24, 33-35 and 37-47 are pending in the instant Office action and will be examined herein.

### ***Withdrawn-Objections to the Specification***

2. The previous objection of the Sequence Listing filed on 2/4/2004 shows as if the nucleic acid "at" translates into an amino acid Ile (see page 49 in the sequence listing); wherein the "at" does not encode Ile is withdrawn by virtue of Applicants' amendment of sequence listing filed on 6/16/2008, i.e., deleting the text of Ile at the end.

### ***Withdrawn-Claim Objections***

3. The previous objection of Claims 20, 22, 23, 34-36 because Claims 20 and 34 are identical; Claims 22 and 35 are identical; and Claims 23 and 36 are identical; is withdrawn by virtue of Applicants' amendment.

***Withdrawn-Claim Rejections - 35 USC § 102***

4. The previous rejection of Claims 19, 20, 22 and 33-35 under 35 U.S.C. 102(b) as being anticipated by Peter et al. (Journal of Bacteriology, 1996, Volume 178, pages 5229-5234) as evidenced by Pisabarro et al. (1993 May, Journal of Bacteriology, Vol. 175, pp. 2743-2749 as cited in IDS) is withdrawn by virtue of Applicants' amendment (i.e., adding a novel nucleotide sequence encoding the polypeptide SEQ ID NO: 2 which is patented in US Patent 6,927,046 from the parent application 09/722,441; and limiting the nucleotide encoding SEQ ID NO: 19 which is a fragment of full length Orf2 polypeptide in Claims 33-35) and reconsideration by the Examiner.

***Withdrawn-Claim Rejections - 35 USC § 103***

5. The previous rejection of Claims 19-20, 22, 24, 33-35, and 37 under 35 U.S.C. 103(a) as being unpatentable over Pisabarro et al. (1993 May, Journal of Bacteriology, Vol. 175, pp. 2743-2749 as cited in IDS) in view of Labarre et al (1993, Journal of Bacteriology, Vol. 175, p. 1001-1007, as cited previous office actions) and Hirano et al. (US Pat. 6,090,597, Jul 18, 2000, as cited in previous office actions) is withdrawn by virtue of Applicants' amendment (i.e., adding a nucleotide sequence encoding novel polypeptide SEQ ID NO: 2 which is patented in US Patent 6,927,046 from the parent application 09/722,441 and limiting the nucleotide encoding the polypeptide consisting SEQ ID NO: 19 which is a fragment of full length Orf2 polypeptide in Claims 33-35 which is not an obvious fragment).

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 33-35 and 37 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility. Claims 33-35 are drawn to an isolated polynucleotide molecule (or a host cell comprising said polynucleotide) comprising a nucleotide sequence encoding the polypeptide consisting of the amino acid sequence of SEQ ID NO: 19 (i.e., N-terminal portion having 122 amino acids from the full length gene orf2 encoding the polypeptide with no known function); wherein said polynucleotide molecule is integrated into the chromosome of cell of the genus *Corynebacterium*. Claim 37 is drawn to a method for selecting a transformed host cell comprising: transforming a *Corynebacterium* species host cell with a vector comprising a polynucleotide molecule comprising a nucleotide sequence encoding the polypeptide consisting of the amino acid sequence of SEQ ID NO: 19. However, the encoded polypeptide of SEQ ID NO: 19 has no known function and/or no utility. In view of Example 8 and Figure 22 which disclose the vector or cells comprising (emphasis added) a coding region of the polynucleotide that encodes the SEQ ID NO: 19 (truncated orf2 which is located at the end of depB, see Figure 22 filed on 9/5/2006) is useful for increased production of lysine (see NRRL-B11474::pDElia2<sub>FCS</sub>+KDBHL or NRRL B30360 on top of page 66). However, the Example 8 does not support the utility of claimed polynucleotide encoding the polypeptide consisting SEQ ID NO: 19, the host having said polynucleotide, or a method for selecting the host. The instant specification does not disclose any

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significant utility of polynucleotide encoding the polypeptide consist of the amino acid sequence of SEQ ID NO: 19.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 19-20, 22-24 and 38-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 31-34 of U.S. Patent No. 6,927,046.

It is noted that all sequences identified with SEQ ID NOs in instant case are identical to sequences (including the number in SEQ ID NO) disclosed in the U.S. Patent No. 6,927,046 (see Sequence Alignment in the attachment below). Although the

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conflicting claims are not identical, they are not patentably distinct from each other because Claim 1 in US Patent 6,927,046 is drawn to an isolated polynucleotide molecule comprising a nucleotide sequence encoding the polypeptide sequence of SEQ ID NO: 2 (which is identical to instant SEQ ID NO: 2) which encompasses any additional genes such as a polynucleotide encoding the **SEQ ID NO: 19**, the nucleotide **SEQ ID NO: 18**, and the host cell **NRRL B30360** and method of making selecting the transformed host cell having said nucleotides, disclosed as preferred embodiment in the specification in §5 lines 43-50. As polynucleotides such as that of within NRRL B30360 are disclosed as preferred embodiments of polynucleotides encoding SEQ ID NO:2 of the patent, it would have been obvious to one of ordinary skill in the art to select this polynucleotide as the polynucleotide comprising SEQ ID NO:2 and thus the instant Claims **19-20, 23-24** are not patentably distinct from claims 1-10 of the patent. See also the detailed description of vector pDElia2<sub>FCS</sub>+KDBHL construct and the preparation of NRRL B30360 in Example 8 in the US Patent 6,927,046 (which is identical to instant Figure 22). For the same reasons above, instant Claims **38-42** are obvious to one of ordinary skill in the art over Claim 1 of U.S. Patent No. 6,927,046 which encompassing an additional polynucleotide such as a polynucleotide encoding the SEQ ID NO: 19 and the nucleotide SEQ ID NO: 1, and polynucleotide encoding polypeptide SEQ ID NO: 1, 4, 6, 8, 10, 14 and/or 21. For the same reasons above, instant method Claims **43-47** are obvious to one of ordinary skill in the art over Claims 31-34 of U.S. Patent No. 6,927,046 which encompassing an additional polynucleotide such as a polynucleotide

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encoding the SEQ ID NO: 19 and the nucleotide SEQ ID NO: 1, and polynucleotide encoding polypeptide SEQ ID NO: 1, 4, 6, 8, 10, 14 and/or 21.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 11AM-7:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/  
Examiner, Art Unit 1656

/Rebecca E. Prouty/  
Primary Examiner,  
Art Unit 1652